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Amendment
Attorney Docket No. S63.2B-9720-US01

Remarks

This Amendment is in response to the Final Office Action dated **November 2, 2005**. Each of the rejections is discussed below.

35 USC 112

Claims 1-4, 6, 11-12 and 22 are rejected under 35 USC 112, second paragraph, as being indefinite. As to claim 1, the Office Action states that

it is unclear how the inflatable members constructed and arranged (assumedly by itself?) such that "no contacting portion encircles the balloon catheter".

Applicant considers the claim language to be definite. Nevertheless, for the sake of forwarding the prosecution, Applicants have, without prejudice or disclaimer, replaced the language in question. Withdrawal of the rejection is respectfully requested.

35 USC 102

Claims 1-6, 11-12, 14, 22, 25-26, 28-29 and 64-67 are rejected under 35 U S C 102(b) as being anticipated by Edwards et al (US 5899917).

Independent Claim 1 and Claims Dependent Therefrom

Re Claims 1-4, 6, 11, 1 and 22

Claim 1 has been amended, without prejudice or disclaimer, to include the recitation that each inflatable member extends part of the way about the channel but does not encircle the channel. This feature is not disclosed in Figs. 7 and 8a of Edwards. The Office Action has identified outer balloon 810 and angioplasty balloon 820 as constituting "a plurality of inflatable members (810,820) defining a channel". Outer balloon 820 of Edwards, however, encircles the "channel" between it and inner balloon 810. At least for this reason, Edwards does not anticipate claim 1 or claims 2-4, 6, 11, 12, 22 and 28-29 dependent therefrom.

Claim 6 further recites the presence of "a rigid tube in which the plurality of inflatable members are constrained, the tube having a first end with a first opening and a second end with a second opening and a passage therethrough". The Office Action identifies inner shaft

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760 of Edwards as constituting the recited "rigid tube". Applicant disagrees. The so-called "plurality of inflatable members" of Edwards are not constrained *in* inner shaft 760. At least for this additional reason, claim 6 is not anticipated by Edwards.

Claim 11 further recites that the plurality of inflatable members are disposed in one or more spirals about the channel. The Office Action asserts that this feature is disclosed in Figs. 7 and 8a of Edwards but does not indicate where the spiral is located. Applicant is unable to find a spiral in Figs. 7 and 8a of Edward and therefore, for this additional reason, does not consider Edwards to anticipate this claim. If the Examiner disagrees, Applicant requests that the spiral be clearly pointed out in the next Office Action.

Claim 22 recites that the balloon contacting portion is made of a compliant material and the remainder of the inflatable member is made of a non-compliant material.

The Office Action states:

...where the balloon contacting portion is made of a compliant material and non-compliant materials such as latex, PHI, Polyethylene or silicone (see col 20, lines 60-62 and col. 22, lines 53-55)....

The text in question reads as follows:

so composition is injected through a lumen 1270^A that is
attached to the surface of the elastic balloon 1250. FIG. 12F
depicts a finished stent 1280 formed by the conversion of the
col. 20, lines 60-62

material is extruded when the balloons 1920 are expanded
and occluding the tubular organ in which the stents are to be
located. The balloons can be made of a silicone/elastomer.
col. 22. lines 53-55.

Applicant fails to find any teaching in the above quotations, of an inflatable member having a balloon contacting portion made of a compliant material and the remainder of the inflatable member being made of a non-compliant material. At most, there is a teaching of a balloon made of a balloon made of a "silicone/elastomer".

Re Claims 28 and 29

Claims 28 and 29 depend from claim 8. Claim 8 has been indicated to contain allowable subject matter. As such, claims 28 and 29 are seen to contain allowable subject matter

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for the same reasons that claim 8 contains allowable subject matter. Applicant therefore requests notification that claims 28 and 29 contain allowable subject matter and are allowable.

Re Independent Claim 5

Independent claim 5 is directed to a device a body comprising a plurality of inflatable members defining a channel therebetween. The claim includes the recitation that the inflatable members are generally tubular and have a generally wedge shaped cross-section. Applicant is unable to discern inflatable members having a wedge shaped cross-section in Figs. 7 and 8a of Edwards. As such, withdrawal of the anticipation rejection is requested.

Re Independent Claim 14

Claim 14 is directed to the combination of a device for configuring an inflatable balloon of a balloon catheter assembly and a balloon portion of a balloon catheter assembly. The device comprises a body comprising a plurality of inflatable members defining a channel therebetween. The balloon portion of a balloon catheter assembly is removably disposed in the channel.

Edwards discloses a balloon within a balloon. To the extent, for the sake of argument, that the space between the balloons could be considered a channel, the Edwards device lacks a balloon portion of a balloon catheter assembly removably disposed in the channel. At least for this reason, claim 14 is not anticipated by Edwards. Further, the limitations of the inflatable members applying an inward force and each of the inflatable members extending only part of the way about the channel are also not met. At least for these reasons, claim 14 is not anticipated by Edwards.

Re Independent Claim 25 and Claim 26 Dependent Therefrom

. As to claims 25-26, the Office Action fails to show where each of the steps of the claim are taught in Edwards. For example, the Office Action has not shown where at least the following steps of:

"disposing a medical balloon between the inflatable members",

"at least partially deflating the medical balloon, the inwardly deformed portions of the

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medical balloon forming a plurality of balloon folds"; and

"removing the inflatable members from about the medical balloon"
are disclosed.

At least for this reason, the rejection is inappropriate. If the Examiner maintains the rejection, Applicant requests that the Examiner point out where each of features of the claims are recited.

Re Independent Claim 64 and Claim 65-67 Dependent Therefrom

Claims 64 and 65-67 dependent therefrom all recite the presence of a body comprising a plurality of inflatable members defining a channel therebetween, the channel sized to accommodate at least a portion of the expandable member. The inflatable members are arranged side-by-side about the channel, each of the inflatable members extending only part of the way about the channel.

To the extent, for the sake of argument, that the inner and outer balloons of Edwards are considered 'inflatable members', the limitation of 'each of the inflatable members extending only part of the way about the channel' is not met. The outer balloon, for example, extends all the way about the channel. At least for this reason, claims 64-67 are not anticipated by Edwards.

Further concerning claims 65 and claims 66-67 dependent therefrom, figs. 7 and 8a do not disclose a rigid tube **in which** the plurality of inflatable members are constrained. The 'rigid tube' 760 referred to in the Office Action does not have a plurality of 'inflatable members' constrained therein. At least for this additional reason, claims 65-67 are not anticipated by Edwards.

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Conclusion

At least for the above discussed reasons, the claims are believed to be patentable over Edwards. Applicant requests withdrawal of the rejections. Applicant also requests that the application be passed to allowance.

Respectfully submitted,
VIDAS, ARRETT & STEINKRAUS

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By: 

James M. Urzedowski
Registration No.: 48596

6109 Blue Circle Drive, Suite 2000
Minnetonka, MN 55343-9185
Telephone: (952) 563-3000
Facsimile: (952) 563-3001

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